

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/4/2009 has been entered.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Derek Allen (on behalf of Craig Siman) on 1/14/10.

The application has been amended as follows:

IN THE CLAIMS:

1. Please cancel claims 1-8.
2. In claim 9, in line 6, please **delete** "less than about 50% water;" and **insert** "about 10% to about 45% water;".

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the prior art does not teach or suggest an oral methylphenidate HCl solution comprising about 0.1 mg/ml to about 10 mg/ml methylphenidate HCl, and about 0.5 mg/ml to about 5.0 mg/ml of at least one organic acid, with the organic acid and methylphenidate HCl being dissolved in a solvent system comprising about 10-45% of water, about 30-70% of at least one polyol solvent and about 10-70% of at least one glycol solvent.

The closest prior art is Midha (US Patent 6,127,385) in view of Epstein et al. (US PgPub 2002/0103162). Midha teaches oral solutions of methylphenidate that is dissolved in propylene glycol and an organic acid. Midha does not teach the amounts of the different components or water. Epstein teaches oral pharmaceutical preparations comprised of methylphenidate in water, polyols and antioxidants. However, neither reference teaches the amounts of each components listed.

Applicants have provided a Declaration in an effort to distinguish their invention from the prior art and to concentrate on the importance of the amounts claimed. In particular, the Declaration of Clifford J. Herman shows tests that were conducted in which concentrations of water were adjusted at 35%, 70% or 90% in the compositions of the present inventions and were analyzed for TA, which is the primary route of methylphenidate HCl degradation. Results show that solutions having a water content of greater than 50% contain significantly more TA than the solutions prepared having water contents of less than 50%. Tests were also run to show stability of the solutions with amounts of an organic acid of about 0.5 mg/ml to about 5.0 mg/ml. Solutions with

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0.25 mg/ml, 2.5 mg/ml or 7.5 mg/ml were tested and it was shown that solutions having either 0.25 mg/ml or 7.5 mg/ml contained significantly more TA than the composition with 2.5 mg/ml.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627